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Dated: 5-24-06

Signature:

(Abby Berghella)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

John F. SHANLEY *et al.*

Application No.: 10/729,631

Filing Date: December 5, 2003

For: EXPANDABLE MEDICAL DELIVERY
DEVICE FOR DELIVERY OF
BENEFICIAL AGENT

Art Unit: 3738

Examiner: Blanco, Javier G.

Attorney Ref. No.: P032 C1

REPLY BRIEF FOR APPELLANT

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

COMES NOW APPELLANT to present this Reply Brief in response to the Examiner's Answer mailed 5 April 2006 in the above-captioned patent application. 37 C.F.R. § 41.41.

For the following additional reasons, and in response to the arguments presented in the Examiner's Answer, Appellant respectfully submits that the final rejection of each of Claims 49-51, 53, 56-62, 74-78, and 81-86 in this application is in error, and therefore respectfully requests reversal of the rejections.

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I. THE EXAMINER'S ANSWER REPEATS THE ERRORS OF THE OFFICE ACTIONS

The Examiner's Answer, like the Office Actions in this application, includes clear fact-finding errors concerning the content of the prior art, which errors are not harmless, and applies incorrect legal standards, and therefore the conclusions of law in the Office Actions are necessarily in error.

In general, the summaries in the Examiner's Answer of Appellant's arguments in the Brief filed 18 January 2006 are gross oversimplifications, and Appellant respectfully requests the Board to refer to Appellant's Brief for complete explanations of the errors in the appealed rejections.

Appellant responds herein to each of the Examiner's Answer's items by reference to its letter designation.

Items A and H

In response to items "A" and "H", the Examiner's Answer does not attempt to address the fact that *Santini*'s disclosure is fatally flawed and does not enable a person of ordinary skill in the art to make the hypothetical 'monolithic' embodiment. In the first full paragraph of page 4 of the Examiner's Answer (copied at item "H"), Mr. Blanco appears to address some of Appellant's arguments concerning *Santini*; however, all Mr. Blanco actually states is that *Santini* hypothesizes about a 'monolithic' embodiment. Mr. Blanco repeats the same text from *Santini* that has been copied repeatedly throughout the prosecution of this application, but does not and cannot make the jump from hypothesis to enablement. Ultimately, Mr. Blanco's arguments in the Final Office Action and the Examiner's Answer are of the same ilk as *Santini*'s: they both wish they could provide a 'monolithic' embodiment, but neither can provide sufficient details, guidance, or reasoning to enable it. Mr. Blanco thus makes a fundamental mistake in applying the doctrine of anticipation, that of concluding that a thing is enabled merely because it is stated in a printed publication. Mr. Blanco does not defend his conclusory logic in the Examiner's

Answer simply because it is indefensible, and fails to detail how *Santini* allegedly enables the hypothetical ‘monolithic’ embodiment because he cannot perform that impossible task.

Items B and K

In response to items “B” and “K” in the Examiner’s Answer, Mr. Blanco appears to correctly copy a portion of Claim 49 (item “B” only), but again misreads the claim. Claim 49 requires, *inter alia*, that the first active agent itself is arranged for delivery according to a first release profile, the second active agent itself is arranged for delivery according to a second release profile, and that the first and second release profiles are different. Mr. Blanco argues that, because of the presence of reservoir cap 530b between two layers 540a, 540b, “the release profiles will inherently be different.” What Mr. Blanco has failed to appreciate throughout this prosecution is that the different release profiles are characteristics of the active agents themselves, and not of the structures with which they form an expandable medical device. Mr. Blanco thus mistakes the reservoir cap 530b for an active agent, which it plainly is not.

In item “K”, Mr. Blanco references a portion of Claim 49 which is not present in the claims addressed in item “K” (74, 82, 83), and thus plainly has misread the claims’ limitations throughout prosecution. Mr. Blanco’s comments in item “K” are therefore simply inapplicable to Claims 74, 82, and 83.

Items C and L

In response to items “C” and “L” in the Examiner’s Answer, Appellant points out that Mr. Blanco first misreads the claims, accusing a positively recited, structural limitation of being a non-limiting “intended purpose”. More specifically, Mr. Blanco ignores the recitations in Claims 50 and 75 that the first and second active layers “are arranged” to be delivered to a mural side of the device body. While broadly recited, the phrase positively recites a structural characteristic of the active layers which cannot be ignored, as Mr. Blanco has done, in comparing the prior art to the claimed subject matter.

Mr. Blanco then appears to acknowledge this error and attempts to address a fundamental defect in *Santini*'s disclosure: *Santini*'s device delivers drugs to its luminal side, while the claim plainly requires a configuration to deliver active agent to the mural side. Mr. Blanco does not fully allege that *Santini*'s device's structures would anticipate the claimed combinations, instead tacitly acknowledging the differences, yet insinuating obviousness:

... the skilled artisan will be left with the choice of deciding the direction of drug delivery, depending on the intended purpose. If the drug delivery reservoirs are disposed into the stent, then the drugs will be exposed (after degradation of the barrier layer) to either the mural or luminal side of the stent.

(Examiner's Answer, page 5, first full paragraph)

This passage in the Examiner's Answer plainly infers an obviousness-type test for patentability, while attempting to justify a rejection for anticipation under section 102. Appellant strongly objects to Mr. Blanco attempting to inject a new rejection, namely one based on 35 U.S.C. § 103(a), into this record at this late stage of prosecution without complying with 37 C.F.R. § 41.39(a)(2). More specifically, nowhere does Mr. Blanco designate a new ground of rejection in the Examiner's Answer, and therefore its inclusion is plainly improper. In addition to a new ground of rejection, however, the foregoing statement can be viewed as further evidence of Mr. Blanco's misapplication of the applicable patentability principles in this application, wherein Mr. Blanco applies standards for patentability under section 103 when making rejections under section 102.

Items D and M

In response to items "D" and "M" in the Examiner's Answer, the Examiner's Answer plainly does not address the fact that *Santini* does not identically disclose the subject matter of Claims 51 and 76. Contrary to Mr. Blanco's unsupported statements, *Santini* does not mention "anti-proliferatives", and does not describe the use in a stent of both "anti-proliferative" and "anti-inflammatory" agents as recited in the combinations of Claims 51 and 76. The statement in

the Examiner's Answer at the top of page 6 and the middle of page 9, "[t]he use of stents carrying anti-proliferative and/or anti-inflammatory drugs is well known in the art", is, like Mr. Blanco's attempt to address the 'mural' limitation of Claims 50 and 75, the use of section 103 standards to a section 102 rejection. The passage in *Santini* to which Mr. Blanco refers (column 2, lines 28-32) does not support this contention, and merely states:

In another embodiment, the microchip device is integrated into a stent for the delivery of drugs, such as anti-restenosis drugs or such as pravastatin or other hypertension medications.

Items E and O

In response to items "E" and "O" in the Examiner's Answer, in which Mr. Blanco again alleges that *Santini*'s reservoir cap 530b is read on by the barrier layer recited in the combinations of Claims 53 and 78, Appellant notes that he again misreads the scope of the claims. From Claim 51, from which Claim 53 depends, and from Claim 77, from which Claim 78 depends, the barrier layer must be "adjacent a luminal side of the device body"; contrary to this requirement, reservoir cap 530b is embedded in the middle of *Santini*'s microchip, and is thus not read on by this limitation. Claims 53's and 78's further requirements that the barrier layer be formed within the openings does not change the analysis, and *Santini*'s reservoir cap 530a is plainly positioned outside of the opening.

Items F and P

In response to items "F" and "P" in the Examiner's Answer, in which the Examiner's Answer points to column 6, lines 13-47, and column 9, lines 5-7, and alleges that *Santini*'s biodegradable reservoir caps are read on by Claims 56's and 81's recitations that the first and second release profiles are designed to coordinate with cellular biochemical processes, Appellant again disagrees. Mr. Blanco also accuses this positive, structural limitation of being "functional language". Appellant first notes that it is the first and second release profiles that are "designed to coordinate with cellular biochemical processes", and not some other claimed structure which

might correspond to a reservoir cap. Nowhere has Mr. Blanco explained how it is that a biodegradable cap is somehow “designed to coordinate with cellular biochemical processes”, while Appellant has explained that, in fact, *Santini*’s device’s drugs are provided without regard to such biochemical processes. Mr. Blanco also confuses the issues by misreading the claim as including merely functional language, when Claims 56 and 81 instead include broad, positively recited, structural limitations.

Items G, J, and Q

Concerning the Examiner’s Answer’s items “G”, “J”, and “Q” in response to Claims 84’s, 85’s, and 86’s limitation that “the plurality of openings are laser drilled through holes”, and Appellant’s arguments in support thereof, Mr. Blanco alleges that these claims are each a ‘product-by-process’ claim; Appellant disagrees. At most, the limitations “wherein the plurality of openings are laser drilled through holes” may be considered ‘product-by-process’ limitations; Each of Claims 84-86 as a whole is not a product-by-process claim. Mr. Blanco then copies a portion of M.P.E.P. § 2113, apparently to support his contention that *Santini* includes a disclosure that anticipates Claims 84-86, but does not provide any explanation of how *Santini*’s frustoconical microchip reservoirs are somehow read on by the phrase “laser drilled through holes”. The Examiner’s Answer, like the Final Office Action, is therefore fatally flawed because it does not even allege facts, or provide a rational explanation, that could support a finding of anticipation by the prior art.

Item N

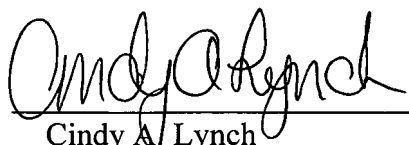
Concerning the Examiner’s Answer’s item “N”, Appellant has demonstrated that *Santini* does not enable a ‘monolithic’ embodiment, and therefore only the embodiment in which a microchip is mounted to the interior surface of *Santini*’s tube can be available as prior art. In that embodiment, the backing plate 550 is positioned away from the luminal surface of the tube, and therefore has a configuration exactly opposite to that of the claimed combinations.

II. CONCLUSION

For at least the foregoing reasons, Appellant respectfully submits that the rejections of the claims in this patent application are in error, and therefore respectfully requests reversal thereof.

Respectfully submitted,

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